# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## The interaction effect of aerobic exercise and vitamin D supplementation on serum levels of apelin, vaspin and inflammatory factors in postmenopausal women with metabolic syndrome

## Protocol summary

**Study aim**

Evaluation of the interactional effect of aerobic exercise and vitamin D supplementation on serum levels of apelin, vaspin and inflammatory factors in postmenopausal women with metabolic syndrome

**Design**

For this purpose, 48 postmenopausal women with metabolic syndrome will be randomly divided into four groups: aerobic training+ vitamin D supplementation, aerobic training, vitamin D supplementation and control. Supplementation included approximately 50,000 IU or placebo per week for eight weeks. The aerobic training protocol includes 40 to 60 minutes of aerobic exercise with a maximum intensity of 60 to 75% of the heart rate maximum, 3 times a week for eight weeks.

**Settings and conduct**

This clinical trial study will be conducted on the effects of aerobic training with Vit D supplementation on metabolic syndrome patients of Kermanshah in pre-test and post-test form, under the supervision of the Faculty of Physical Education of Sanandaj Branch of Azad University

**Participants/Inclusion and exclusion criteria**

Inclusion criteria will include evaluation of metabolic syndrome based on ATPIII criteria, being in menopause age, 25-OHD serum levels between 10 and 20 ng/ml, not having a specific diet and regular exercise program in the past year. Exclusion criteria include; presence of other cardiovascular disease, surgical treatment of obesity or severe weight loss, and the presence of any other chronic disease or skeletal disorders

**Intervention groups**

Aerobic training (placebo); Vitamin D supplementation (no AT); Aerobic training with vitamin D supplements (AT+Vit D); and Control (placebo+no AT)

**Main outcome variables**

levels of vitamin D, lipid profile, body composition, blood pressure, insulin, glucose, vaspin, apelin, interleukin-6, interleukin beta-1, tumor necrosis factor alpha, C-reactive protein

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20200122046217N1**
Registration date: **2020-08-14, 1399/05/24**
Registration timing: **retrospective**

Last update: **2020-08-14, 1399/05/24**
Update count: **0**

**Registration date**

2020-08-14, 1399/05/24

**Registrant information**

**Name**

Parivash Najafi nazar abadi

**Name of organization / entity**

No.9, Adab Ave, Pasdaran Blvd, Islamic Azad University Sanandaj Branch

**Country**

Iran (Islamic Republic of)

**Phone**

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2020-07-10, 1399/04/20

**Expected recruitment end date**

2020-08-10, 1399/05/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The interaction effect of aerobic exercise and vitamin D supplementation on serum levels of apelin, vaspin and inflammatory factors in postmenopausal women with metabolic syndrome

**Public title**

The effect of exercise and vitamin D in postmenopausal women with metabolic syndrome

**Purpose**

Health service research

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

confirmation of metabolic syndrome based on ATPIII criteria Not having a specific diet and regular exercise program in the past year 25-OHD serum levels between 10 and 20 ng/ml Being in menopause age

**Exclusion criteria:**

Presence of other cardiovascular disease Surgical treatment of obesity Presence of any other chronic disease or skeletal disorders severe weight loss

**Age**

From **50 years** old to **60 years** old

**Gender**

Female

**Phase**

1

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **48**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In the present study, a table of random numbers will be used for randomization. In which subjects are randomly assigned to separate groups to compare the effects of intervention methods.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Used

**Assignment**

Factorial

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Kurdistan University of Medical Sciences

**Street address**

No. 8, Pasdaran Blvd, Sanandaj Province, Kurdistan University of Medical Sciences

**City**

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**Province**

Kurdistan

**Postal code**

6617913446

**Approval date**

2020-01-07, 1398/10/17

**Ethics committee reference number**

IR.MUK.REC.1398.241

## Health conditions studied

### 1

**Description of health condition studied**

Metabolic syndrome disease

**ICD-10 code**

E88.81

**ICD-10 code description**

Metabolic syndrome

## Primary outcomes

### 1

**Description**

Vitamin D levels

**Timepoint**

Prior to the beginning and at the end of the study

**Method of measurement**

By blood sampling

### 2

**Description**

Anthropometric indices

**Timepoint**

Before the study starts and after the study ends

**Method of measurement**

Using INBODY test

### 3

**Description**

Lipid profile

**Timepoint**

Before the study starts and after it ended.

**Method of measurement**

Blood sampling

### 4

**Description**

Vaspin

**Timepoint**

Before the study starts and after it ended.

**Method of measurement**

Blood sampling

**5**

**Description**

Apelin

**Timepoint**

Before the study starts and after it ended.

**Method of measurement**

Blood sampling

**6**

**Description**

interleukin-6

**Timepoint**

Before the study starts and after it ended.

**Method of measurement**

Blood sampling

**7**

**Description**

Interleukin beta-1

**Timepoint**

Before the study starts and after it ended.

**Method of measurement**

Blood sampling

**8**

**Description**

C- reactive protein

**Timepoint**

Before the study starts and after it ended.

**Method of measurement**

Blood sampling

**9**

**Description**

Tumor necrosis factor alpha

**Timepoint**

Before the study starts and after it ended.

**Method of measurement**

Blood sampling

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

Intervention group: The aerobic training + vitamin D supplementation Intervention will be consists of 20-40 minutes of aerobic exercise at 60% - 75% of HRmax, 3 times a week for eight weeks and vitamin D supplementation will be receiving vitamin D (~50000 IU • week for eight weeks).

**Category**

Lifestyle

**2**

**Description**

Intervention group: Aerobic training consists of 20-40 minutes of aerobic exercise at 60% - 75% of HRmax, 3 times a week for eight weeks.

**Category**

Lifestyle

**3**

**Description**

Intervention group: Vitamin D supplementation includes receiving vitamin D (~50000 IU • week for eight weeks).

**Category**

Lifestyle

**4**

**Description**

Control group: receiving placebo and no aerobic training for eight weeks

**Category**

Other

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Emam Ali hospital

**Full name of responsible person**

Parivash Najafi Nazar Abadi

**Street address**

Shahid Beheshti Blvd. - Imam Ali Cardiovascular Hospital

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Zaher Etemad

**Street address**

No. 9, Faculty of Physical Education and Sports Sciences, Sanandaj, Adab St., Daneshgah Blvd., Islamic Azad University, Sanandaj Branch

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zaher.etemad2020@gmail.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

slamic Azad University, Sanandaj Branch

**Proportion provided by this source**

10

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Razi University

**Full name of responsible person**

Rastegar Hoseini

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Sport Medicine

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Full name of responsible person**

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**Position**

PhD Student

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Sport Medicine

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**
Yes - There is a plan to make this available
**Informed Consent Form**
Yes - There is a plan to make this available
**Clinical Study Report**
Yes - There is a plan to make this available
**Analytic Code**
Not applicable
**Data Dictionary**
Not applicable
**Title and more details about the data/document**
All data will be record in the SPSS software and will be available.
**When the data will become available and for how long**
Availability will start nine months after publishing all papers
**To whom data/document is available**
Only available for researchers in academic and scientific institutions
**Under which criteria data/document could be used**
All data can be used as reference
**From where data/document is obtainable**
pnajafi1354@gmail.com
**What processes are involved for a request to access data/document**
If the explanation for data request would be convincing it will be given in 3 days.
**Comments**
not having any